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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,313	04/28/2008	Samuel S. Murray	38586-330002	4686

1923 7590 03/10/2010  
MCDERMOTT, WILL & EMERY LLP  
Attn: IP Department  
227 WEST MONROE STREET  
SUITE 4400  
CHICAGO, IL 60606-5096

EXAMINER
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ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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03/10/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,313	<b>Applicant(s)</b> MURRAY ET AL.	
	<b>Examiner</b> David S. Romeo	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-23, 25, 29, 32 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-5, 8-23, 25, 29, 32 and 36-49 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

The amendment filed 04/28/2008 has been entered. Claims 1–5, 8–23, 25, 29, 32 and 36–49 are pending.

### *Election/Restrictions*

5           Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

10          Group I, claim(s) 1-5, 11–13, 22, 23, 25 and 38–43, drawn to a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

15          Group II, claim(s) 8–10, 29 and 44–46, drawn to a nucleic acid molecule encoding a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

15          Group III, claim(s) 14 and 15, drawn to a method of assaying the biological activity of BBP.

20          Group IV, claim(s) 16–20, drawn to a method of enhancing or inducing osteogenesis or calcification comprising administering in vivo a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

25          Group V, claim(s) 21, drawn to a method of enhancing osteogenesis comprising administering ex vivo a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

30          Group VI, claim(s) 32 and 47–49 (in part), drawn to an antibody that binds a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

30          Group VII, claim(s) 32 and 47–49 (in part), drawn to an antibody that binds a peptide comprising the amino acid sequence of SEQ ID NO: 4 or a fragment thereof.

35          Group VIII, claim(s) 36 (in part), drawn to a method detecting BBP utilizing an antibody that binds a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

Group IX, claim(s) 36 (in part), drawn to a method of detecting BBP utilizing an antibody that binds a peptide comprising the amino acid sequence of SEQ ID NO: 4 or a fragment thereof.

5

Group X, claim(s) 37, drawn to a method detecting a nucleic acid molecule encoding BBP utilizing a nucleic acid molecule encoding a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof.

10

The inventions listed as Groups I–X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In order for the groups to have unity of invention it is necessary that the inventive concept, i.e., a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a fragment thereof, be a contribution over the prior art. However, the international search report filed with the present application indicates that the groups cannot be considered novel or cannot be considered to involve an inventive concept. Therefore, the groups do not fulfill the requirements for unity of invention. Moreover, although SEQ ID NO: 1 and SEQ ID NO: 4 possibly share a common utility, they do not share a substantial structural feature disclosed as being essential to that utility.

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This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

25

The species are as follows:

BMP-2, BMP-4, BMP-7 and DBM.

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are

5 generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the

10 elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

BMP-2 corresponds to claims 5, 11, 15, 16, 19, 21 and 23.

15 BMP-4 corresponds to claims 5 and 15.

BMP-7 corresponds to claims 5 and 15.

DBM corresponds to claims 5, 11, 16, 19, 21 and 23

The following claim(s) are generic: 5, 11, 15, 16, 19, 21 and 23.

20

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The inventive concept linking these species is a peptide comprising the amino acid sequence of SEQ ID NO: 1 or a

25 fragment thereof. In order for the species to have unity of invention it is necessary that the inventive concept be a contribution over the prior art. However, the international search report filed with the present application indicates that the inventive concept cannot be considered novel or cannot be considered to involve an inventive concept. Therefore, the species do not fulfill the requirements for unity of invention.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

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requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does  
5 not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim  
10 remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise  
15 require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process  
20 claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

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are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the

5 above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY NICKOL, CAN BE REACHED AT (571)272-0939.

15 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-0835.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

20 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

25 /DAVID S ROMEO/  
PRIMARY EXAMINER, ART UNIT 1647

DSR

March 5, 2010